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Date of Deposit: July 2, 2004

PATENT  
Attorney Docket No.: 20695C-005900  
Client Ref. No.: R-237.00US



I hereby certify that this is being deposited with the United States Postal Service "Express Mail Post Office to Address" service under 37 CFR 1.10 on the date indicated above and is addressed to:

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

By: Janet L. Newmaker  
Janet L. Newmaker

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Scheifflinger et al.

Application No.: 09/661,992

Filed: September 14, 2000

For: FACTOR IX/FACTOR IXA  
ACTIVATING ANTIBODIES AND  
ANTIBODY DERIVATIVES

Customer No.: 20350

Confirmation No. 8902

Examiner: Haddad, Maher M.

Art Unit: 1644

DECLARATION UNDER 37 C.F.R. 1.808

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The undersigned, Scott L. Ausenhus, attorney of record authorized to act on behalf of the Applicants and Assignee in matters relating to the subject Patent Application, does hereby declare and state that:

1. The cell line designated 98/B1, described at, *e.g.*, line 29, page 23, of the above-captioned application, was deposited at the European Collection of Cell Cultures on September 9, 1999, and given accession number 99090925. The address of the European Collection of Cell Cultures (ECACC) is Salisbury, Wiltshire, SP4 OJG, UK. The deposit was

made pursuant to the provisions of the Budapest Treaty. A copy of the ECACC receipt is attached as Exhibit A.

2. The cell line designated 198/A1, described at, *e.g.*, line 30, page 23, of the above-captioned application, was deposited at the European Collection of Cell Cultures on September 9, 1999, and given accession number 99090924. The address of the European Collection of Cell Cultures (ECACC) is Salisbury, Wiltshire, SP4 OJG, UK. The deposit was made pursuant to the provisions of the Budapest Treaty. A copy of the ECACC receipt is attached as Exhibit B.

3. The cell line designated 198/BB1, described at, *e.g.*, line 30, page 23, of the above-captioned application, was deposited at the European Collection of Cell Cultures on September 9, 1999, and given accession number 99090926. The address of the European Collection of Cell Cultures (ECACC) is Salisbury, Wiltshire, SP4 OJG, UK. The deposit was made pursuant to the provisions of the Budapest Treaty. A copy of the ECACC receipt is attached as Exhibit C.

4. The cell line designated 193/AO, described at, *e.g.*, line 31, page 23, of the above-captioned application, was deposited at the European Collection of Cell Cultures on December 16, 1999, and given accession number 99121614. The address of the European Collection of Cell Cultures (ECACC) is Salisbury, Wiltshire, SP4 OJG, UK. The deposit was made pursuant to the provisions of the Budapest Treaty. A copy of the ECACC receipt is attached as Exhibit D.

5. The cell line designated 196/C4, described at, *e.g.*, line 31, page 23, of the above-captioned application, was deposited at the European Collection of Cell Cultures on December 16, 1999, and given accession number 99121615. The address of the European Collection of Cell Cultures (ECACC) is Salisbury, Wiltshire, SP4 OJG, UK. The deposit was made pursuant to the provisions of the Budapest Treaty. A copy of the ECACC receipt is attached as Exhibit E.

6. The cell line designated 198/D1, described at, *e.g.*, line 32, page 23, of the above-captioned application, was deposited at the European Collection of Cell Cultures on December 16, 1999, and given accession number 99121616. The address of the European Collection of Cell Cultures (ECACC) is Salisbury, Wiltshire, SP4 OJG, UK. The deposit was made pursuant to the provisions of the Budapest Treaty. A copy of the ECACC receipt is attached as Exhibit F.

7. The cell line designated 198/T2, described at, *e.g.*, line 33, page 23, of the above-captioned application, was deposited at the European Collection of Cell Cultures on December 16, 1999, and given accession number 99121617. The address of the European Collection of Cell Cultures (ECACC) is Salisbury, Wiltshire, SP4 OJG, UK. The deposit was made pursuant to the provisions of the Budapest Treaty. A copy of the ECACC receipt is attached as Exhibit G.

8. The cell line designated 198/G2, described at, *e.g.*, line 33, page 23, of the above-captioned application, was deposited at the European Collection of Cell Cultures on December 16, 1999, and given accession number 99121618. The address of the European Collection of Cell Cultures (ECACC) is Salisbury, Wiltshire, SP4 OJG, UK. The deposit was made pursuant to the provisions of the Budapest Treaty. A copy of the ECACC receipt is attached as Exhibit H.

9. The cell line designated 198/AC1, described at, *e.g.*, line 34, page 23, of the above-captioned application, was deposited at the European Collection of Cell Cultures on December 16, 1999, and given accession number 99121619. The address of the European Collection of Cell Cultures (ECACC) is Salisbury, Wiltshire, SP4 OJG, UK. The deposit was made pursuant to the provisions of the Budapest Treaty. A copy of the ECACC receipt is attached as Exhibit I.

10. The cell line designated 198/U2, described at, *e.g.*, line 34, page 23, of the above-captioned application, was deposited at the European Collection of Cell Cultures on

December 16, 1999, and given accession number 99121620. The address of the European Collection of Cell Cultures (ECACC) is Salisbury, Wiltshire, SP4 OJG, UK. The deposit was made pursuant to the provisions of the Budapest Treaty. A copy of the ECACC receipt is attached as Exhibit J.

11. The cell lines identified in paragraphs 1-10 above will be maintained at the ECACC and replaced in the event of mutation, nonviability or destruction for a period of at least five (5) years after the most recent request for release of a sample was received by ATCC, or for a period of at least thirty (30) years after the date of the deposit, or during the enforceable life of the related patent, whichever period is longer.

12. All restrictions on the availability to the public of the cell lines identified in paragraphs 1-10 above will be irrevocably removed upon the issuance of a patent from the above-captioned application.

13. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: July 2, 2004



---

Scott L. Ausenhus, Reg. No. 42,271

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, 8<sup>th</sup> Floor  
San Francisco, California 94111-3834  
Tel: (303) 571-4000  
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SLA/jln

60251672 v1



# Centre for Applied Microbiology and Research & European Collection of Cell Cultures

This document certifies that Cell Culture  
(Deposit Ref. 99090925 ) has been accepted as a patent deposit,  
in accordance with  
The Budapest Treaty of 1977,  
with the European Collection of Cell Cultures on 9<sup>th</sup> September 1999

Dr P J Packer,  
Quality Manager, ECACC

European Collection of Cell Cultures, Centre for Applied Microbiology & Research  
Salisbury, Wiltshire SP4 0JG, UK.

Tel: +44 1980 612512 Fax: +44 1980 611315

E-Mail: [ecacc@camr.org.uk](mailto:ecacc@camr.org.uk) Web Site: [www.camr.org.uk](http://www.camr.org.uk)

**CAMR**  
Today's Research  
Tomorrow's Health



No. FS33819

## APPENDIX 3

Page 14

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

TO

INTERNATIONAL FORM

BAXTER AG  
INDUSTRIESTRASSE 67  
1220 VIENNA  
AUSTRIANAME AND ADDRESS  
OF DEPOSITOR

## I. IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the  
DEPOSITOR:

198/B1

Accession number given by the  
INTERNATIONAL DEPOSITORY AUTHORITY:

99090925

## II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

☒ X

A scientific description



A proposed taxonomic designation

(Mark with a cross where applicable)

## III. RECEIPT AND ACCEPTANCE

This International Depository Authority accepts the microorganism identified under I above,  
which was received by it on 9<sup>th</sup> September 1999 (date of the original deposit)<sup>1</sup>

## IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I above was received by this International  
Depository Authority on (date of the original deposit) and  
A request to convert the original deposit to a deposit under the Budapest Treaty  
was received by it on (date of receipt of request for conversion)

## IV. INTERNATIONAL DEPOSITORY AUTHORITY

Name: Dr P J Packer

Signature(s) of person(s) having the power  
to represent the International Depository  
Authority or of authorized official(s):Address: ECACC  
CAMR  
Porton Down  
Salisbury SP4 0JG

Date:

11/3/00 *PJ Packer*<sup>1</sup> Where Rule 6.4(d) applies, such date is the date on which the status of international depository  
authority was acquired

## APPENDIX 3

Page 24

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

TO

BAXTER AG  
INDUSTRIESTRASSE 67  
1220 VIENNA  
AUSTRIA

## VIABILITY STATEMENT

Issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified on the following pageNAME AND ADDRESS OF THE PARTY  
TO WHOM THE VIABILITY OF STATEMENT  
IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
Name: BAXTER AG  Address: INDUSTRIESTRASSE 67 1220 VIENNA AUSTRIA	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:  99090925  Date of the deposit or of the transfer: 9 <sup>th</sup> September 1999
II. VIABILITY STATEMENT	
The viability of the microorganism identified under II above was tested on <sup>2</sup> . On that date, the said microorganism was  <input checked="checked" type="checkbox"/> <sup>3</sup> viable  <input type="checkbox"/> <sup>3</sup> no longer viable	

- 1 Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).
- 2 In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.
- 3 Mark with a cross the applicable box.

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED <sup>4</sup>	
<p>198/B1 - 99090925</p> <p>VIABILITY TESTS COMPLETED USING THE DYE EXCLUSION METHOD (TRYPAN BLUE).</p>	
V. INTERNATIONAL DEPOSITARY AUTHORITY	
Name: Dr P J Packer ECACC CAMR Address: Porton Down Salisbury Wiltshire SP4 0JG	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):  Date: 1/3/00 <i>P.J. Packer</i>

4 Fill in if the information has been requested and if the results of the test were negative.





# Centre for Applied Microbiology and Research & European Collection of Cell Cultures

This document certifies that Cell Culture  
(Deposit Ref. 99090924 ) has been accepted as a patent deposit,  
in accordance with  
The Budapest Treaty of 1977,  
with the European Collection of Cell Cultures on 9<sup>th</sup> September 1999

Dr P J Packer,  
Quality Manager, ECACC

European Collection of Cell Cultures, Centre for Applied Microbiology & Research  
Salisbury, Wiltshire SP4 0JG, UK.

Tel: +44 1980 612512 Fax: +44 1980 611315

E-Mail: [ecacc@camr.org.uk](mailto:ecacc@camr.org.uk) Web Site: [www.camr.org.uk](http://www.camr.org.uk)

**CAMR**  
Today's Research  
Tomorrow's Health



No. FS33819

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

TO

INTERNATIONAL FORM

BAXTER AG  
INDUSTRIESTRASSE 67  
1220 VIENNA  
AUSTRIA

NAME AND ADDRESS  
OF DEPOSITOR

<b>I. IDENTIFICATION OF THE MICROORGANISM</b>	
Identification reference given by the DEPOSITOR:  CLONE 198/A1	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY:  99090924
<b>II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION</b>	
The microorganism identified under I above was accompanied by: <div style="margin-top: 10px;"> <input checked="checked" type="checkbox"/> A scientific description  <input type="checkbox"/> A proposed taxonomic designation         </div> (Mark with a cross where applicable)	
<b>III. RECEIPT AND ACCEPTANCE</b>	
This International Depository Authority accepts the microorganism identified under I above, which was received by it on 9 <sup>th</sup> September 1999 (date of the original deposit) <sup>1</sup>	
<b>IV. RECEIPT OF REQUEST FOR CONVERSION</b>	
The microorganism identified under I above was received by this International Depository Authority on (date of the original deposit) and A request to convert the original deposit to a deposit under the Budapest Treaty was received by it on (date of receipt of request for conversion)	
<b>IV. INTERNATIONAL DEPOSITORY AUTHORITY</b>	
Name: Dr P J Packer  Address: ECACC CAMR Porton Down Salisbury SP4 0JG	Signature(s) of person(s) having the power to represent the International Depository Authority or of authorized official(s):  Date: <i>P. Packer 26/11/99</i>

<sup>1</sup> Where Rule 6.4(d) applies, such date is the date on which the status of international depository authority was acquired

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BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

TO

BAXTER AG  
INDUSTRIESTRASSE 67  
1220 VIENNA  
AUSTRIA

VIABILITY STATEMENT  
Issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITORY AUTHORITY  
identified on the following page

NAME AND ADDRESS OF THE PARTY  
TO WHOM THE VIABILITY OF STATEMENT  
IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
Name: BAXTER AG  Address: INDUSTRIESTRASSE 67 1220 VIENNA AUSTRIA	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY:  99090924  Date of the deposit or of the transfer: 9 <sup>th</sup> September 1999
II. VIABILITY STATEMENT	
<p>The viability of the microorganism identified under II above was tested on <sup>1</sup>. On that date, the said microorganism was</p> <div data-bbox="94 1276 172 1331"><input checked="" type="checkbox"/></div> <sup>3</sup> viable <p><input type="checkbox"/> <sup>3</sup> no longer viable</p>	

- 1 Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).
- 2 In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.
- 3 Mark with a cross the applicable box.

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED <sup>4</sup>	
<p>CLONE 198/A1 - 99090924</p> <p>COUNTED USING TRYPAN BLUE EXCLUSION METHOD CELL COUNT WAS <math>3 \times 10^6</math> AND 70% VIABLE IN 48 HOURS.</p>	
V. INTERNATIONAL DEPOSITARY AUTHORITY	
<p>Name: Dr P J Packer ECACC CAMR Address: Porton Down Salisbury Wiltshire SP4 0JG</p>	<p>Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):</p> <p>Date: <i>P.J. Packer</i> 26/11/99</p>

<sup>4</sup> Fill in if the information has been requested and if the results of the test were negative.



# Centre for Applied Microbiology and Research & European Collection of Cell Cultures

This document certifies that Cell Culture  
(Deposit Ref. 99090926 ) has been accepted as a patent deposit,  
in accordance with  
The Budapest Treaty of 1977,  
with the European Collection of Cell Cultures on 9<sup>th</sup> September 1999

*P. J. Packer*

Dr P J Packer,  
Quality Manager, ECACC

European Collection of Cell Cultures, Centre for Applied Microbiology & Research  
Salisbury, Wiltshire SP4 0JG, UK.

Tel: +44 1980 612512 Fax: +44 1980 611315

E-Mail: [ecacc@camr.org.uk](mailto:ecacc@camr.org.uk) Web Site: [www.camr.org.uk](http://www.camr.org.uk)

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Tomorrow's Health



No. FS33819

## APPENDIX 3

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BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

TO

INTERNATIONAL FORM

BAXTER AG  
INDUSTRIESTRASSE 67  
1220 VIENNA  
AUSTRIANAME AND ADDRESS  
OF DEPOSITOR

## I. IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the  
DEPOSITOR:

CLONE 198/BB1

Accession number given by the  
INTERNATIONAL DEPOSITARY AUTHORITY:

99090926

## II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

☒

A scientific description

☐

A proposed taxonomic designation

(Mark with a cross where applicable)

## III. RECEIPT AND ACCEPTANCE

This International Depositary Authority accepts the microorganism identified under I above,  
which was received by it on 9<sup>th</sup> September 1999 (date of the original deposit)<sup>1</sup>

## IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I above was received by this International  
Depositary Authority on (date of the original deposit) and  
A request to convert the original deposit to a deposit under the Budapest Treaty  
was received by it on (date of receipt of request for conversion)

## IV. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Dr P J Packer

Address: ECACC  
CAMR  
Porton Down  
Salisbury SP4 0JGSignature(s) of person(s) having the power  
to represent the International Depositary  
Authority or of authorized official(s):

Date:

P.J. Packer 26/11/99

1 Where Rule 6.4(d) applies, such date is the date on which the status of international depositary  
authority was acquired

## APPENDIX 3

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BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

TO

BAXTER AG  
INDUSTRIESTRASSE 67  
1220 VIENNA  
AUSTRIA

## VIABILITY STATEMENT

Issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified on the following pageNAME AND ADDRESS OF THE PARTY  
TO WHOM THE VIABILITY OF STATEMENT  
IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
<p>Name: BAXTER AG</p> <p>Address: INDUSTRIESTRASSE 67 1220 VIENNA AUSTRIA</p>	<p>Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:  99090926</p> <p>Date of the deposit or of the transfer: 9<sup>th</sup> September 1999</p>
II. VIABILITY STATEMENT	
<p>The viability of the microorganism identified under II above was tested on <sup>2</sup>. On that date, the said microorganism was</p> <p><input checked="checked" type="checkbox"/> <sup>3</sup> viable</p> <p><input type="checkbox"/> <sup>3</sup> no longer viable</p>	

- 1 Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).
- 2 In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.
- 3 Mark with a cross the applicable box.

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED <sup>4</sup>

CLONE 198/BB1 - 99090926

COUNTED USING TRYPAN BLUE EXCLUSION METHOD VIABLE CELL COUNT WAS  $3 \times 10^6$  AND 70% VIABLE IN 48 HOURS.

## V. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Dr P J Packer  
ECACC CAMR  
Address: Porton Down  
Salisbury  
Wiltshire  
SP4 0JG

Signature(s) of person(s) having the power  
to represent the International Depositary  
Authority or of authorized official(s):

Date: P.J. Packer 25/11/99

<sup>4</sup> Fill in if the information has been requested and if the results of the test were negative.





# Centre for Applied Microbiology and Research & European Collection of Cell Cultures

This document certifies that Cell Culture  
(Deposit Ref. 99121614 ) has been accepted as a patent deposit,  
in accordance with  
The Budapest Treaty of 1977,  
with the European Collection of Cell Cultures on 16<sup>th</sup> December 1999

*P J Packer*

Dr P J Packer,  
Quality Manager, ECACC

European Collection of Cell Cultures, Centre for Applied Microbiology & Research  
Salisbury, Wiltshire SP4 0JG, UK.

Tel: +44 1980 612512 Fax: +44 1980 611315  
E-Mail: [ecacc@camr.org.uk](mailto:ecacc@camr.org.uk) Web Site: [www.camr.org.uk](http://www.camr.org.uk)

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No. FS33819

## Certificate of Analysis

**Product Description**  
**Accession Number**

**Clone 193/A0**  
**99121614**

---

**Test Description:** Cell Count, Viability and confluency of cells on resuscitation from frozen.

**Acceptance Criterion/Specification:** were judged acceptable if they meet the following criteria:

- >70% viable cells
- >2 x 10<sup>6</sup> viable cells/ml
- Confluent within 2 days

**Date:** 13/01/00

**Result:**

Viable Cell Count:	6.7 x 10 <sup>6</sup> cells/ml
Percentage Viability:	78%
Confluent within:	2 days
Overall Result:	PASS

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**Test Description:** The Detection of Mycoplasma by Isolation on Mycoplasma Pig Serum Agar and in Mycoplasma Horse Serum Broth.  
SOP QC/MYCO/01/02

**Acceptance Criterion/Specification:** All positive controls (*M. pneumoniae* & *M. orale*) must show evidence of mycoplasma by typical colony formation on agar plates. Broths are subcultured onto Mycoplasma Pig Serum Agar where evidence of mycoplasma by typical colony formation is evaluated. All negative control agar plates must show no evidence of microbial growth.

The criteria for a positive test result is evidence of mycoplasma by typical colony formation on agar. A negative result will show no such evidence.


**Test Number:** 20395

**Date:** 07/02/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

---

Authorised by..........ECACC, Head of Quality.....24/2/00..... Date

## Certificate of Analysis

**Product Description**  
**Accession Number**

**Clone 193/A0**  
**99121614**

---

**Test Description:** Detection of Mycoplasma using a Vero indicator cell line and Hoechst 33258 fluorescent detection system.  
SOP QC/MYCO/07/05

**Acceptance Criterion/Specification:** The Vero cells in the negative control are clearly seen as fluorescing nuclei with no cytoplasmic fluorescence. Positive control (*M. orale*) must show evidence of mycoplasma as fluorescing nuclei plus extra nuclear fluorescence of mycoplasma DNA. Positive test results appear as extra nuclear fluorescence of mycoplasma DNA. Negative results show no cytoplasmic fluorescence.

**Test Number:** 20395

**Date:** 07/02/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

---

**Test Description:** Detection of bacteria and fungi by isolation on Tryptone Soya Broth (TSB) and in Fluid Thioglycollate Medium (FTGM). SOP QC/BF/01/02

**Acceptance Criterion/Specification:** All positive controls (*Bacillus subtilis*, *Clostridium sporogenes* and *Candida albicans*) show evidence of microbial growth (turbidity) and the negative controls show no evidence of microbial growth (clear).  
The criteria for a positive test is turbidity in any of the test broths. All broths should be clear for negative test result.

**Test Number:** 20395

**Date:** 07/02/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

---

Authorised by.....*PJH*.....ECACC, Head of Quality.....*24/2/00*..... Date

## APPENDIX 3

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BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

TO

INTERNATIONAL FORM

BAXTER AG  
INDUSTRIESTRASSE 67  
1220 VIENNA  
AUSTRIA

NAME AND ADDRESS  
OF DEPOSITOR

## I. IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the  
DEPOSITOR:

HYBRIDOMA CLONE 193/AO

Accession number given by the  
INTERNATIONAL DEPOSITORY AUTHORITY:

99121614

## II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

☒ X

A scientific description



A proposed taxonomic designation

(Mark with a cross where applicable)

## III. RECEIPT AND ACCEPTANCE

This International Depository Authority accepts the microorganism identified under I above,  
which was received by it on 16<sup>th</sup> December 1999 (date of the original deposit)<sup>1</sup>

## IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I above was received by this International  
Depository Authority on (date of the original deposit) and  
A request to convert the original deposit to a deposit under the Budapest Treaty  
was received by it on (date of receipt of request for conversion)

## IV. INTERNATIONAL DEPOSITORY AUTHORITY

Name: Dr P J Packer

Signature(s) of person(s) having the power  
to represent the International Depository  
Authority or of authorized officials(s):

Address: ECACC  
CAMR  
Porton Down  
Salisbury SP4 0JG

Date:

23/3/00 PJP

<sup>1</sup> Where Rule 6.4(d) applies, such date is the date on which the status of international depository  
authority was acquired

## APPENDIX 3

Page 24

BUDAPEST TREATY ON THE INTERNATIONAL  
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FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

TO

BAXTER AG  
INDUSTRIESTRASSE 67  
1220 VIENNA  
AUSTRIA

## VIABILITY STATEMENT

Issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITORY AUTHORITY  
identified on the following pageNAME AND ADDRESS OF THE PARTY  
TO WHOM THE VIABILITY OF STATEMENT  
IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
Name: BAXTER AG  Address: INDUSTRIESTRASSE 67 1220 VIENNA AUSTRIA	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY:  99121614  Date of the deposit or of the transfer: 16 <sup>th</sup> December 1999
II. VIABILITY STATEMENT	
The viability of the microorganism identified under II above was tested on <sup>1</sup> . On that date, the said microorganism was	
<input checked="checked" type="checkbox"/> <sup>3</sup> viable	
<input type="checkbox"/> <sup>3</sup> no longer viable	

- 1 Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).
- 2 In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.
- 3 Mark with a cross the applicable box.

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED <sup>4</sup>

99121614 - HYBRIDOMA CLONE 193/AO

CELLS WERE RESUSCITATED AND COUNTED ACCORDING TO THE TRYPON BLUE EXCLUSION METHOD.

## V. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Dr P J Packer  
ECACC CAMR  
Address: Porton Down  
Salisbury  
Wiltshire  
SP4 0JG

Signature(s) of person(s) having the power  
to represent the International Depositary  
Authority or of authorized official(s):

Date: 23/3/00 P.J. Packer

<sup>4</sup> Fill in if the information has been requested and if the results of the test were negative.

Centre for Applied Microbiology and Research  
&  
European Collection of Cell Cultures

This document certifies that Cell Culture  
(Deposit Ref. 99121615 ) has been accepted as a patent deposit,  
in accordance with  
The Budapest Treaty of 1977,  
with the European Collection of Cell Cultures on 16<sup>th</sup> December 1999

PJ Packer

Dr P J Packer,  
Quality Manager, ECACC

European Collection of Cell Cultures, Centre for Applied Microbiology & Research  
Salisbury, Wiltshire SP4 0JG, UK.

Tel: +44 1980 612512 Fax: +44 1980 611315

E-Mail: [ecacc@camr.org.uk](mailto:ecacc@camr.org.uk) Web Site: [www.camr.org.uk](http://www.camr.org.uk)

**CAMR**  
Today's Research  
Tomorrow's Health



No. FS33819

## Certificate of Analysis

**Product Description**  
**Accession Number**

**Clone 196/C4**  
**99121615**

---

**Test Description:** Cell Count, Viability and confluency of cells on resuscitation from frozen.

**Acceptance Criterion/Specification:** were judged acceptable if they meet the following criteria:

- >70% viable cells
- >2 x 10<sup>6</sup> viable cells/ml
- Confluent within 2 days

**Date:** 13/01/00

**Result:**

Viable Cell Count:	4.7 x 10 <sup>6</sup> cells/ml
Percentage Viability:	70%
Confluent within:	2 days
Overall Result:	PASS

---

---

**Test Description:** The Detection of Mycoplasma by Isolation on Mycoplasma Pig Serum Agar and in Mycoplasma Horse Serum Broth.  
SOP QC/MYCO/01/02

**Acceptance Criterion/Specification:** All positive controls (*M. pneumoniae* & *M. orale*) must show evidence of mycoplasma by typical colony formation on agar plates. Broths are subcultured onto Mycoplasma Pig Serum Agar where evidence of mycoplasma by typical colony formation is evaluated. All negative control agar plates must show no evidence of microbial growth.  
The criteria for a positive test result is evidence of mycoplasma by typical colony formation on agar. A negative result will show no such evidence.

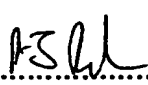
**Test Number:** 20392

**Date:** 07/02/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

---

Authorised by..........ECACC, Head of Quality...24/12/00... Date



# Certificate of Analysis

**Product Description**  
**Accession Number**

**Clone 196/C4**  
**99121615**

---

**Test Description:** Detection of Mycoplasma using a Vero indicator cell line and Hoechst 33258 fluorescent detection system.  
SOP QC/MYCO/07/05

**Acceptance Criterion/Specification:** The Vero cells in the negative control are clearly seen as fluorescing nuclei with no cytoplasmic fluorescence. Positive control (*M. orale*) must show evidence of mycoplasma as fluorescing nuclei plus extra nuclear fluorescence of mycoplasma DNA. Positive test results appear as extra nuclear fluorescence of mycoplasma DNA. Negative results show no cytoplasmic fluorescence.

**Test Number:** 20392

**Date:** 07/02/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

---

**Test Description:** Detection of bacteria and fungi by isolation on Tryptone Soya Broth (TSB) and in Fluid Thioglycollate Medium (FTGM). SOP QC/BF/01/02

**Acceptance Criterion/Specification:** All positive controls (*Bacillus subtilis*, *Clostridium sporogenes* and *Candida albicans*) show evidence of microbial growth (turbidity) and the negative controls show no evidence of microbial growth (clear).  
The criteria for a positive test is turbidity in any of the test broths. All broths should be clear for negative test result.

**Test Number:** 20392

**Date:** 07/02/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

---

Authorised by..........ECACC, Head of Quality.......... Date

## APPENDIX 3

Page 14

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

TO

BAXTER AG  
INDUSTRIESTRASSE 67  
1220 VIENNA  
AUSTRIA

INTERNATIONAL FORM

NAME AND ADDRESS  
OF DEPOSITOR

## I. IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the  
DEPOSITOR:

HYBRIDOMA CLONE 196/C4

Accession number given by the  
INTERNATIONAL DEPOSITARY AUTHORITY:

99121615

## II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

- ☒ A scientific description
- ☐ A proposed taxonomic designation

(Mark with a cross where applicable)

## III. RECEIPT AND ACCEPTANCE

This International Depositary Authority accepts the microorganism identified under I above,  
which was received by it on 16<sup>th</sup> December 1999 (date of the original deposit)<sup>1</sup>

## IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I above was received by this International  
Depositary Authority on (date of the original deposit) and  
A request to convert the original deposit to a deposit under the Budapest Treaty  
was received by it on (date of receipt of request for conversion)

## IV. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Dr P J Packer

Address: ECACC  
CAMR  
Porton Down  
Salisbury SP4 0JGSignature(s) of person(s) having the power  
to represent the International Depositary  
Authority or of authorized official(s):

Date: 23/3/00 P.J. Packer

1 Where Rule 6.4(d) applies, such date is the date on which the status of international depositary  
authority was acquired

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

<p>TO</p> <p>BAXTER AG INDUSTRIESTRASSE 67 1220 VIENNA AUSTRIA</p>	<p>VIABILITY STATEMENT</p> <p>Issued pursuant to Rule 10.2 by the INTERNATIONAL DEPOSITARY AUTHORITY identified on the following page</p>
--	---

NAME AND ADDRESS OF THE PARTY  
TO WHOM THE VIABILITY OF STATEMENT  
IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
<p>Name: BAXTER AG</p> <p>Address: INDUSTRIESTRASSE 67 1220 VIENNA AUSTRIA</p>	<p>Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:</p> <p>99121615</p> <p>Date of the deposit or of the transfer: 16<sup>th</sup> December 1999</p>
<p>II. VIABILITY STATEMENT</p>	
<p>The viability of the microorganism identified under II above was tested on</p> <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="width: 40%;"> <p><input checked="checked" type="checkbox"/> <sup>3</sup> viable</p> <p><input type="checkbox"/> <sup>3</sup> no longer viable</p> </div> <div style="width: 60%;"> <p><sup>2</sup>. On that date, the said microorganism was</p> </div> </div>	

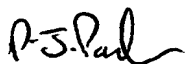
- 1 Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).
- 2 In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.
- 3 Mark with a cross the applicable box.

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED <sup>4</sup>	
<p>99121615 - HYBRIDOMA CLONE 196/C4</p> <p>CELLS WERE RESUSCITATED AND COUNTED ACCORDING TO THE TRYPON BLUE EXCLUSION METHOD.</p>	
V. INTERNATIONAL DEPOSITARY AUTHORITY	
<p>Name: Dr P J Packer ECACC CAMR</p> <p>Address: Porton Down Salisbury Wiltshire SP4 0JG</p>	<p>Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):</p> <p>Date: 28/3/00 P.J. Packer</p>

4 Fill in if the information has been requested and if the results of the test were negative.

Centre for Applied Microbiology and Research  
&  
European Collection of Cell Cultures

This document certifies that Cell Culture  
(Deposit Ref. 99121616 ) has been accepted as a patent deposit,  
in accordance with  
The Budapest Treaty of 1977,  
with the European Collection of Cell Cultures on 16<sup>th</sup> December 1999



---

Dr P J Packer,  
Quality Manager, ECACC

---

European Collection of Cell Cultures, Centre for Applied Microbiology & Research  
Salisbury, Wiltshire SP4 0JG, UK.

Tel: +44 1980 612512 Fax: +44 1980 611315

E-Mail: [ecacc@camr.org.uk](mailto:ecacc@camr.org.uk) Web Site: [www.camr.org.uk](http://www.camr.org.uk)

**CAMR**  
Today's Research  
Tomorrow's Health



No. FS33819

## Certificate of Analysis

**Product Description**  
**Accession Number**

**Clone 198/D1**  
**99121616**

---

**Test Description:** Cell Count, Viability and confluency of cells on resuscitation from frozen.

**Acceptance Criterion/Specification:** were judged acceptable if they meet the following criteria:

- >70% viable cells
- >2 x 10<sup>5</sup> viable cells/ml
- Confluent within 2 days

**Date:** 13/01/00

**Result:**

Viable Cell Count:	6.3 x 10 <sup>6</sup> cells/ml
Percentage Viability:	55%
Confluent within:	2 days
Overall Result:	PASS (With a deviation, grows really well within 48 hours)

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---

**Test Description:** The Detection of Mycoplasma by Isolation on Mycoplasma Pig Serum Agar and in Mycoplasma Horse Serum Broth.  
SOP QC/MYCO/01/02

**Acceptance Criterion/Specification:** All positive controls (*M. pneumoniae* & *M. orale*) must show evidence of mycoplasma by typical colony formation on agar plates. Broths are subcultured onto Mycoplasma Pig Serum Agar where evidence of mycoplasma by typical colony formation is evaluated. All negative control agar plates must show no evidence of microbial growth.  
The criteria for a positive test result is evidence of mycoplasma by typical colony formation on agar. A negative result will show no such evidence.


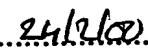
**Test Number:** 20393

**Date:** 07/02/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

---

Authorised by..........ECACC, Head of Quality.......... Date

## Certificate of Analysis

**Product Description**  
**Accession Number**

**Clone 198/D1**  
**99121616**

---

**Test Description:** Detection of Mycoplasma using a Vero indicator cell line and Hoechst 33258 fluorescent detection system.  
SOP QC/MYCO/07/05

**Acceptance Criterion/Specification:** The Vero cells in the negative control are clearly seen as fluorescing nuclei with no cytoplasmic fluorescence. Positive control (*M. orale*) must show evidence of mycoplasma as fluorescing nuclei plus extra nuclear fluorescence of mycoplasma DNA. Positive test results appear as extra nuclear fluorescence of mycoplasma DNA. Negative results show no cytoplasmic fluorescence.

**Test Number:** 20393

**Date:** 07/02/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

---

**Test Description:** Detection of bacteria and fungi by isolation on Tryptone Soya Broth (TSB) and in Fluid Thioglycollate Medium (FTGM). SOP QC/BF/01/02

**Acceptance Criterion/Specification:** All positive controls (*Bacillus subtilis*, *Clostridium sporogenes* and *Candida albicans*) show evidence of microbial growth (turbidity) and the negative controls show no evidence of microbial growth (clear).  
The criteria for a positive test is turbidity in any of the test broths. All broths should be clear for negative test result.


**Test Number:** 20393

**Date:** 07/02/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

---

Authorised by..........ECACC, Head of Quality..24/2/00.... Date

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

TO INTERNATIONAL FORM

BAXTER AG  
INDUSTRIESTRASSE 67  
1220 VIENNA  
AUSTRIA

NAME AND ADDRESS  
OF DEPOSITOR

<b>I. IDENTIFICATION OF THE MICROORGANISM</b>	
Identification reference given by the DEPOSITOR:  HYBRIDOMA CLONE 198/D1	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY:  99121616
<b>II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION</b>	
The microorganism identified under I above was accompanied by: <div style="margin-top: 10px;"> <input checked="checked" type="checkbox"/> A scientific description           <div style="margin-left: 20px;"><input type="checkbox"/> A proposed taxonomic designation</div> </div> (Mark with a cross where applicable)	
<b>III. RECEIPT AND ACCEPTANCE</b>	
This International Depository Authority accepts the microorganism identified under I above, which was received by it on 16 <sup>th</sup> December 1999 (date of the original deposit) <sup>1</sup>	
<b>IV. RECEIPT OF REQUEST FOR CONVERSION</b>	
The microorganism identified under I above was received by this International Depository Authority on (date of the original deposit) and A request to convert the original deposit to a deposit under the Budapest Treaty was received by it on (date of receipt of request for conversion)	
<b>IV. INTERNATIONAL DEPOSITORY AUTHORITY</b>	
Name: Dr P J Packer  Address: ECACC CAMR Porton Down Salisbury SP4 0JG	Signature(s) of person(s) having the power to represent the International Depository Authority or of authorized officials(s):  Date: 23/3/00 <i>PJP</i>

1 Where Rule 6.4(d) applies, such date is the date on which the status of international depository authority was acquired



BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

TO

BAXTER AG  
INDUSTRIESTRASSE 67  
1220 VIENNA  
AUSTRIA

## VIABILITY STATEMENT

Issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified on the following page

NAME AND ADDRESS OF THE PARTY  
TO WHOM THE VIABILITY OF STATEMENT  
IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
<p>Name: BAXTER AG</p> <p>Address: INDUSTRIESTRASSE 67 1220 VIENNA AUSTRIA</p>	<p>Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:</p> <p>99121616</p> <p>Date of the deposit or of the transfer: 16<sup>th</sup> December 1999</p>
<p>II. VIABILITY STATEMENT</p>	
<p>The viability of the microorganism identified under II above was tested on <sup>2</sup>. On that date, the said microorganism was</p> <div style="display: flex; margin-top: 10px;"> <div style="margin-right: 20px;"> <input checked="checked" type="checkbox"/> <sup>3</sup> </div> <div> <p>viable</p> </div> </div> <div style="margin-top: 10px;"> <input type="checkbox"/> <sup>3</sup> </div> <div> <p>no longer viable</p> </div>	

- 1      Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).
- 2      In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.
- 3      Mark with a cross the applicable box.

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED <sup>4</sup>	
<p>99121616 - HYBRIDOMA CLONE 198/D1</p> <p>CELLS WERE RESUSCITATED AND COUNTED ACCORDING TO THE TRYPON BLUE EXCLUSION METHOD.</p>	
V. INTERNATIONAL DEPOSITARY AUTHORITY	
<p>Name: Dr P J Packer ECACC CAMR</p> <p>Address: Porton Down Salisbury Wiltshire SP4 0JG</p>	<p>Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):</p> <p>Date: 23/3/00 P-J Packer</p>

4 Fill in if the information has been requested and if the results of the test were negative.

Centre for Applied Microbiology and Research  
&  
European Collection of Cell Cultures

This document certifies that Cell Culture  
(Deposit Ref. 99121617 ) has been accepted as a patent deposit,  
in accordance with  
The Budapest Treaty of 1977,  
with the European Collection of Cell Cultures on 16<sup>th</sup> December 1999

P.J. Packer

Dr P J Packer,  
Quality Manager, ECACC

European Collection of Cell Cultures, Centre for Applied Microbiology & Research  
Salisbury, Wiltshire SP4 0JG, UK.

Tel: +44 1980 612512 Fax: +44 1980 611315

E-Mail: [ecacc@camr.org.uk](mailto:ecacc@camr.org.uk) Web Site: [www.camr.org.uk](http://www.camr.org.uk)

CAMR  
Today's Research  
Tomorrow's Health



No. FS33819

## Certificate of Analysis

**Product Description**  
**Accession Number**

**Clone 198/T2**  
**99121617**

---

**Test Description:** Cell Count, Viability and confluency of cells on resuscitation from frozen.

**Acceptance Criterion/Specification:** were judged acceptable if they meet the following criteria:

- >70% viable cells
- >2 x 10<sup>6</sup> viable cells/ml
- Confluent within 2 days

**Date:** 13/01/00

**Result:**

Viable Cell Count:	1.4 x 10 <sup>7</sup> cells/ml
Percentage Viability:	69%
Confluent within:	2 days
Overall Result:	PASS

---

---

**Test Description:** The Detection of Mycoplasma by Isolation on Mycoplasma Pig Serum Agar and in Mycoplasma Horse Serum Broth.  
SOP QC/MYCO/01/02

**Acceptance Criterion/Specification:** All positive controls (*M. pneumoniae* & *M. orale*) must show evidence of mycoplasma by typical colony formation on agar plates. Broths are subcultured onto Mycoplasma Pig Serum Agar where evidence of mycoplasma by typical colony formation is evaluated. All negative control agar plates must show no evidence of microbial growth.

The criteria for a positive test result is evidence of mycoplasma by typical colony formation on agar. A negative result will show no such evidence.

**Test Number:** 20391

**Date:** 07/02/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

---

Authorised by..........ECACC, Head of Quality.......... Date

# Certificate of Analysis

**Product Description**  
**Accession Number**

**Clone 198/T2**  
**99121617**

---

**Test Description:** Detection of Mycoplasma using a Vero indicator cell line and Hoechst 33258 fluorescent detection system.  
SOP QC/MYCO/07/05

**Acceptance Criterion/Specification:** The Vero cells in the negative control are clearly seen as fluorescing nuclei with no cytoplasmic fluorescence. Positive control (*M. orale*) must show evidence of mycoplasma as fluorescing nuclei plus extra nuclear fluorescence of mycoplasma DNA. Positive test results appear as extra nuclear fluorescence of mycoplasma DNA. Negative results show no cytoplasmic fluorescence.

**Test Number:** 20391

**Date:** 07/02/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

---

**Test Description:** Detection of bacteria and fungi by isolation on Tryptone Soya Broth (TSB) and in Fluid Thioglycollate Medium (FTGM). SOP QC/BF/01/02

**Acceptance Criterion/Specification:** All positive controls (*Bacillus subtilis*, *Clostridium sporogenes* and *Candida albicans*) show evidence of microbial growth (turbidity) and the negative controls show no evidence of microbial growth (clear).  
The criteria for a positive test is turbidity in any of the test broths. All broths should be clear for negative test result.

**Test Number:** 20391

**Date:** 07/02/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

---

Authorised by.....*AS Dale*.....ECACC, Head of Quality.....*24/2/00*..... Date

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

TO

BAXTER AG  
INDUSTRIESTRASSE 67  
1220 VIENNA  
AUSTRIA

INTERNATIONAL FORM

NAME AND ADDRESS  
OF DEPOSITOR

## I. IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the  
DEPOSITOR:

HYBRIDOMA CLONE 198/T2

Accession number given by the  
INTERNATIONAL DEPOSITORY AUTHORITY:

99121617

## II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

- ☒ A scientific description
- ☐ A proposed taxonomic designation

(Mark with a cross where applicable)

## III. RECEIPT AND ACCEPTANCE

This International Depository Authority accepts the microorganism identified under I above,  
which was received by it on 16<sup>th</sup> December 1999 (date of the original deposit)<sup>1</sup>

## IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I above was received by this International  
Depository Authority on (date of the original deposit) and  
A request to convert the original deposit to a deposit under the Budapest Treaty  
was received by it on (date of receipt of request for conversion)

## IV. INTERNATIONAL DEPOSITORY AUTHORITY

Name: Dr P J Packer

Address: ECACC  
CAMR  
Porton Down  
Salisbury SP4 0JG

Signature(s) of person(s) having the power  
to represent the International Depository  
Authority or of authorized official(s):

Date: 23/3/00

PJPade

<sup>1</sup> Where Rule 6.4(d) applies, such date is the date on which the status of international depository  
authority was acquired

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

TO

BAXTER AG  
INDUSTRIESTRASSE 67  
1220 VIENNA  
AUSTRIA

## VIABILITY STATEMENT

Issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITORY AUTHORITY  
identified on the following page

NAME AND ADDRESS OF THE PARTY  
TO WHOM THE VIABILITY OF STATEMENT  
IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
<p>Name: BAXTER AG</p> <p>Address: INDUSTRIESTRASSE 67 1220 VIENNA AUSTRIA</p>	<p>Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY:</p> <p>99121617</p> <p>Date of the deposit or of the transfer: 16<sup>th</sup> December 1999</p>
<p>II. VIABILITY STATEMENT</p> <p>The viability of the microorganism identified under II above was tested on <sup>2</sup>. On that date, the said microorganism was</p> <div style="display: flex; margin-top: 10px;"> <div style="margin-right: 10px;"> <input checked="checked" type="checkbox"/> <sup>3</sup> </div> <div> <p>viable</p> </div> </div> <div style="margin-top: 10px;"> <div style="display: inline-block; width: 40px; height: 20px; border: 1px solid black; margin-right: 10px;"></div> <sup>3</sup> </div> <div> <p>no longer viable</p> </div>	

- 1 Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).
- 2 In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.
- 3 Mark with a cross the applicable box.

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED <sup>4</sup>	
<p>99121617 - HYBRIDOMA CLONE 198/T2</p> <p>CELLS WERE RESUSCITATED AND COUNTED ACCORDING TO THE TRYPON BLUE EXCLUSION METHOD.</p>	
V. INTERNATIONAL DEPOSITARY AUTHORITY	
<p>Name: Dr P J Packer ECACC CAMR</p> <p>Address: Porton Down Salisbury Wiltshire SP4 0JG</p>	<p>Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):</p> <p>Date: 23/3/00 P.J. Packer</p>

<sup>4</sup> Fill in if the information has been requested and if the results of the test were negative.



**Centre for Applied Microbiology and Research  
&  
European Collection of Cell Cultures**

**This document certifies that Cell Culture  
(Deposit Ref. 99121618 ) has been accepted as a patent deposit,  
in accordance with  
The Budapest Treaty of 1977,  
with the European Collection of Cell Cultures on 16<sup>th</sup> December 1999**



**Dr P J Packer,  
Quality Manager, ECACC**

European Collection of Cell Cultures, Centre for Applied Microbiology & Research  
Salisbury, Wiltshire SP4 0JG, UK.

*Tel:* +44 1980 612512 *Fax:* +44 1980 611315

*E-Mail:* [ecacc@camr.org.uk](mailto:ecacc@camr.org.uk) *Web Site:* [www.camr.org.uk](http://www.camr.org.uk)

**CAMR**  
Today's Research  
Tomorrow's Health



No. FS33819

## Certificate of Analysis

**Product Description**  
**Lot Number**

**CLONE 198/G2**  
**99121618**

---

**Test Description:** Cell Count, Viability and confluency of cells on resuscitation from frozen.

**Acceptance Criterion/Specification:** were judged acceptable if they meet the following criteria:

- >70% viable cells
- >2 x 10<sup>6</sup> viable cells/ml
- Confluent within 2 days

**Date:** 12/01/00

**Result:**

Viable Cell Count:	3.4 x 10 <sup>6</sup> cells/ml
Percentage Viability:	74%
Confluent within:	2 days
Overall Result:	PASS

---

---

**Test Description:** The Detection of Mycoplasma by Isolation on Mycoplasma Pig Serum Agar and in Mycoplasma Horse Serum Broth.  
SOP QC/MYCO/01/02

**Acceptance Criterion/Specification:** All positive controls (*M. pneumoniae* & *M. orale*) must show evidence of mycoplasma by typical colony formation on agar plates. Broths are subcultured onto Mycoplasma Pig Serum Agar where evidence of mycoplasma by typical colony formation is evaluated. All negative control agar plates must show no evidence of microbial growth.

The criteria for a positive test result is evidence of mycoplasma by typical colony formation on agar. A negative result will show no such evidence.


**Test Number:** 20576

**Date:** 06/03/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

---

Authorised by..........ECACC, Head of Quality.....10/3/00..... Date

# Certificate of Analysis

**Product Description**  
**Lot Number**

**CLONE 198/G2**  
**99121618**

---

**Test Description:** Detection of Mycoplasma using a Vero indicator cell line and Hoechst 33258 fluorescent detection system.  
SOP QC/MYCO/07/05

**Acceptance Criterion/Specification:** The Vero cells in the negative control are clearly seen as fluorescing nuclei with no cytoplasmic fluorescence. Positive control (*M. orale*) must show evidence of mycoplasma as fluorescing nuclei plus extra nuclear fluorescence of mycoplasma DNA. Positive test results appear as extra nuclear fluorescence of mycoplasma DNA. Negative results show no cytoplasmic fluorescence.

**Test Number:** 20576

**Date:** 06/03/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

---

**Test Description:** Detection of bacteria and fungi by isolation on Tryptone Soya Broth (TSB) and in Fluid Thioglycollate Medium (FTGM). SOP QC/BF/01/02

**Acceptance Criterion/Specification:** All positive controls (*Bacillus subtilis*, *Clostridium sporogenes* and *Candida albicans*) show evidence of microbial growth (turbidity) and the negative controls show no evidence of microbial growth (clear).  
The criteria for a positive test is turbidity in any of the test broths. All broths should be clear for negative test result.

**Test Number:** 20576

**Date:** 06/03/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

---

Authorised by..........ECACC, Head of Quality..10/3/02..... Date

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

TO

BAXTER AG  
INDUSTRIESTRASSE 67  
1220 VIENNA  
AUSTRIA

NAME AND ADDRESS  
OF DEPOSITOR

<b>I. IDENTIFICATION OF THE MICROORGANISM</b>	
Identification reference given by the DEPOSITOR:  HYBRIDOMA CLONE 198/G2	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY:  99121618
<b>II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION</b>	
The microorganism identified under I above was accompanied by:	
<div style="display: flex; flex-direction: column; gap: 10px;"> <div> <input checked="checked" type="checkbox"/> A scientific description         </div> <div> <input type="checkbox"/> A proposed taxonomic designation         </div> </div>	
(Mark with a cross where applicable)	
<b>III. RECEIPT AND ACCEPTANCE</b>	
This International Depository Authority accepts the microorganism identified under I above, which was received by it on 16 <sup>th</sup> December 1999 (date of the original deposit) <sup>1</sup>	
<b>IV. RECEIPT OF REQUEST FOR CONVERSION</b>	
The microorganism identified under I above was received by this International Depository Authority on (date of the original deposit) and A request to convert the original deposit to a deposit under the Budapest Treaty was received by it on (date of receipt of request for conversion)	
<b>IV. INTERNATIONAL DEPOSITORY AUTHORITY</b>	
Name: Dr P J Packer  Address: ECACC CAMR Porton Down Salisbury SP4 0JG	Signature(s) of person(s) having the power to represent the International Depository Authority or of authorized official(s):  Date: 23/3/00 <i>P.J. Packer</i>

<sup>1</sup> Where Rule 6.4(d) applies, such date is the date on which the status of international depository authority was acquired

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

TO

BAXTER AG  
INDUSTRIESTRASSE 67  
1220 VIENNA  
AUSTRIA

## VIABILITY STATEMENT

Issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified on the following page

NAME AND ADDRESS OF THE PARTY  
TO WHOM THE VIABILITY OF STATEMENT  
IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
<p>Name: BAXTER AG</p> <p>Address: INDUSTRIESTRASSE 67 1220 VIENNA AUSTRIA</p>	<p>Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:</p> <p>99121618</p> <p>Date of the deposit or of the transfer: 16<sup>th</sup> December 1999</p>
II. VIABILITY STATEMENT	
<p>The viability of the microorganism identified under II above was tested on <sup>1</sup>. On that date, the said microorganism was</p> <p><input checked="checked" type="checkbox"/> <sup>3</sup> viable</p> <p><input type="checkbox"/> <sup>3</sup> no longer viable</p>	

- 1 Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).
- 2 In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.
- 3 Mark with a cross the applicable box.

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED <sup>4</sup>	
<p>99121618 - HYBRIDOMA CLONE 198/G2</p> <p>CELLS WERE RESUSCITATED AND COUNTED ACCORDING TO THE TRYPON BLUE EXCLUSION METHOD.</p>	
V. INTERNATIONAL DEPOSITARY AUTHORITY	
<p>Name: Dr P J Packer ECACC CAMR</p> <p>Address: Porton Down Salisbury Wiltshire SP4 0JG</p>	<p>Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):</p> <p>Date: 23/3/00 P-J Packer</p>

4 Fill in if the information has been requested and if the results of the test were negative.

# Centre for Applied Microbiology and Research & European Collection of Cell Cultures

This document certifies that Cell Culture  
(Deposit Ref. 99121619 ) has been accepted as a patent deposit,  
in accordance with  
The Budapest Treaty of 1977,  
with the European Collection of Cell Cultures on 16<sup>th</sup> December 1999



Dr P J Packer,  
Quality Manager, ECACC

European Collection of Cell Cultures, Centre for Applied Microbiology & Research  
Salisbury, Wiltshire SP4 0JG, UK.

Tel: +44 1980 612512 Fax: +44 1980 611315

E-Mail: [ecacc@camr.org.uk](mailto:ecacc@camr.org.uk) Web Site: [www.camr.org.uk](http://www.camr.org.uk)

**CAMR**  
Today's Research  
Tomorrow's Health



No. FS33819

## Certificate of Analysis

**Product Description**  
**Accession Number**

**Clone 198/AC1**  
**99121619**

---

**Test Description:** Cell Count, Viability and confluency of cells on resuscitation from frozen.

**Acceptance Criterion/Specification:** were judged acceptable if they meet the following criteria:

- >70% viable cells
- >2 x 10<sup>6</sup> viable cells/ml
- Confluent within 2 days

**Date:** 13/01/00

**Result:**

Viable Cell Count:	1.3 x 10 <sup>7</sup> cells/ml
Percentage Viability:	78%
Confluent within:	2 days
Overall Result:	PASS

---

---

**Test Description:** The Detection of Mycoplasma by Isolation on Mycoplasma Pig Serum Agar and in Mycoplasma Horse Serum Broth.  
SOP QC/MYCO/01/02

**Acceptance Criterion/Specification:** All positive controls (*M. pneumoniae* & *M. orale*) must show evidence of mycoplasma by typical colony formation on agar plates. Broths are subcultured onto Mycoplasma Pig Serum Agar where evidence of mycoplasma by typical colony formation is evaluated. All negative control agar plates must show no evidence of microbial growth.

The criteria for a positive test result is evidence of mycoplasma by typical colony formation on agar. A negative result will show no such evidence.

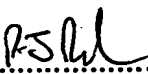

**Test Number:** 20394

**Date:** 07/02/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

---

Authorised by..........ECACC, Head of Quality.......... Date



# Certificate of Analysis

**Product Description**  
**Accession Number**

**Clone 198/AC1**  
**99121619**

---

**Test Description:** Detection of Mycoplasma using a Vero indicator cell line and Hoechst 33258 fluorescent detection system.  
SOP QC/MYCO/07/05

**Acceptance Criterion/Specification:** The Vero cells in the negative control are clearly seen as fluorescing nuclei with no cytoplasmic fluorescence. Positive control (*M. orale*) must show evidence of mycoplasma as fluorescing nuclei plus extra nuclear fluorescence of mycoplasma DNA. Positive test results appear as extra nuclear fluorescence of mycoplasma DNA. Negative results show no cytoplasmic fluorescence.

**Test Number:** 20394

**Date:** 07/02/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

---

**Test Description:** Detection of bacteria and fungi by isolation on Tryptone Soya Broth (TSB) and in Fluid Thioglycollate Medium (FTGM). SOP QC/BF/01/02

**Acceptance Criterion/Specification:** All positive controls (*Bacillus subtilis*, *Clostridium sporogenes* and *Candida albicans*) show evidence of microbial growth (turbidity) and the negative controls show no evidence of microbial growth (clear).  
The criteria for a positive test is turbidity in any of the test broths. All broths should be clear for negative test result.

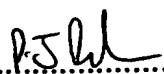
**Test Number:** 20394

**Date:** 07/02/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

---

Authorised by..........ECACC, Head of Quality.....24/2/00..... Date

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

TO

INTERNATIONAL FORM

BAXTER AG  
INDUSTRIESTRASSE 67  
1220 VIENNA  
AUSTRIA

NAME AND ADDRESS  
OF DEPOSITOR

<b>I. IDENTIFICATION OF THE MICROORGANISM</b>	
Identification reference given by the DEPOSITOR:  HYBRIDOMA CLONE 198/AC1	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:  99121619
<b>II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION</b>	
The microorganism identified under I above was accompanied by: <div style="margin-top: 10px;"> <input checked="checked" type="checkbox"/> A scientific description         </div> <div style="margin-top: 10px;"> <input type="checkbox"/> A proposed taxonomic designation         </div> <p>(Mark with a cross where applicable)</p>	
<b>III. RECEIPT AND ACCEPTANCE</b>	
This International Depositary Authority accepts the microorganism identified under I above, which was received by it on 16 <sup>th</sup> December 1999 (date of the original deposit) <sup>1</sup>	
<b>IV. RECEIPT OF REQUEST FOR CONVERSION</b>	
The microorganism identified under I above was received by this International Depositary Authority on (date of the original deposit) and A request to convert the original deposit to a deposit under the Budapest Treaty was received by it on (date of receipt of request for conversion)	
<b>IV. INTERNATIONAL DEPOSITARY AUTHORITY</b>	
Name: Dr P J Packer  Address: ECACC CAMR Porton Down Salisbury SP4 0JG	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):  Date: 23/3/00 <i>PJ Packer</i>

<sup>1</sup> Where Rule 6.4(d) applies, such date is the date on which the status of international depositary authority was acquired

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

TO

BAXTER AG  
INDUSTRIESTRASSE 67  
1220 VIENNA  
AUSTRIA

## VIABILITY STATEMENT

Issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified on the following page

NAME AND ADDRESS OF THE PARTY  
TO WHOM THE VIABILITY OF STATEMENT  
IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
Name: BAXTER AG  Address: INDUSTRIESTRASSE 67 1220 VIENNA AUSTRIA	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:  99121619 Date of the deposit or of the transfer: 16 <sup>th</sup> December 1999
II. VIABILITY STATEMENT	
<p>The viability of the microorganism identified under II above was tested on <sup>1</sup>. On that date, the said microorganism was</p> <p><input checked="checked" type="checkbox"/> <sup>3</sup> viable</p> <p><input type="checkbox"/> <sup>3</sup> no longer viable</p>	

- 1 Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).
- 2 In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.
- 3 Mark with a cross the applicable box.

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED <sup>4</sup>	
<p>99121619 - HYBRIDOMA CLONE 198/AC1</p> <p>CELLS WERE RESUSCITATED AND COUNTED ACCORDING TO THE TRYPON BLUE EXCLUSION METHOD.</p>	
V. INTERNATIONAL DEPOSITARY AUTHORITY	
<p>Name: Dr P J Packer ECACC CAMR</p> <p>Address: Porton Down Salisbury Wiltshire SP4 0JG</p>	<p>Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):</p> <p>Date: 23/3/00 <i>P.J. Packer</i></p>

4 Fill in if the information has been requested and if the results of the test were negative.

Centre for Applied Microbiology and Research  
&  
European Collection of Cell Cultures

This document certifies that Cell Culture  
(Deposit Ref. 99121620 ) has been accepted as a patent deposit,  
in accordance with  
The Budapest Treaty of 1977,  
with the European Collection of Cell Cultures on 16<sup>th</sup> December 1999



Dr P J Packer,  
Quality Manager, ECACC

European Collection of Cell Cultures, Centre for Applied Microbiology & Research  
Salisbury, Wiltshire SP4 0JG, UK.

Tel: +44 1980 612512 Fax: +44 1980 611315

E-Mail: [ecacc@camr.org.uk](mailto:ecacc@camr.org.uk) Web Site: [www.camr.org.uk](http://www.camr.org.uk)

**CAMR**  
Today's Research  
Tomorrow's Health



No. FS33819

**Product Description**  
**Lot Number**

**CLONE 198/U2**  
**99121620**

**Test Description:** Cell Count, Viability and confluency of cells on resuscitation from frozen.

**Acceptance Criterion/Specification:** were judged acceptable if they meet the following criteria:

- **>70% viable cells**
- **>2 x 10<sup>6</sup> viable cells/ml**
- **Confluent within 2 days**

**Date:** 12/01/00

**Result:**

<b>Viable Cell Count:</b>	<b>5.4 x 10<sup>6</sup> cells/ml</b>
<b>Percentage Viability:</b>	<b>89%</b>
<b>Confluent within:</b>	<b>2 days</b>
<b>Overall Result:</b>	<b>PASS</b>

**Test Description:** The Detection of Mycoplasma by Isolation on Mycoplasma Pig Serum Agar and in Mycoplasma Horse Serum Broth.  
SOP OC/MYCO/01/02

**Acceptance Criterion/Specification:** All positive controls (*M. pneumoniae* & *M. orale*) must show evidence of mycoplasma by typical colony formation on agar plates. Broths are subcultured onto Mycoplasma Pig Serum Agar where evidence of mycoplasma by typical colony formation is evaluated. All negative control agar plates must show no evidence of microbial growth. The criteria for a positive test result is evidence of mycoplasma by typical colony formation on agar. A negative result will show no such evidence.

**Test Number:** 20575

**Date:** 06/03/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

Authorised by.....WNL.....ECACC, Head of Quality.....30/5/10..... Date

## Certificate of Analysis

**Product Description**  
**Lot Number**

**CLONE 198/U2**  
**99121620**

---

**Test Description:** Detection of Mycoplasma using a Vero indicator cell line and Hoechst 33258 fluorescent detection system.  
SOP QC/MYCO/07/05

**Acceptance Criterion/Specification:** The Vero cells in the negative control are clearly seen as fluorescing nuclei with no cytoplasmic fluorescence. Positive control (*M. orale*) must show evidence of mycoplasma as fluorescing nuclei plus extra nuclear fluorescence of mycoplasma DNA. Positive test results appear as extra nuclear fluorescence of mycoplasma DNA. Negative results show no cytoplasmic fluorescence.

**Test Number:** 20575

**Date:** 06/03/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

---

**Test Description:** Detection of bacteria and fungi by isolation on Tryptone Soya Broth (TSB) and in Fluid Thioglycollate Medium (FTGM). SOP QC/BF/01/02

**Acceptance Criterion/Specification:** All positive controls (*Bacillus subtilis*, *Clostridium sporogenes* and *Candida albicans*) show evidence of microbial growth (turbidity) and the negative controls show no evidence of microbial growth (clear).  
The criteria for a positive test is turbidity in any of the test broths. All broths should be clear for negative test result.


**Test Number:** 20575

**Date:** 06/03/00

**Result:**

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

---

Authorised by..........ECACC, Head of Quality.....30/5/00... Date

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED <sup>4</sup>	
<p>99121620 - HYBRIDOMA CLONE 198/U2</p> <p>CELLS WERE RESUSCITATED AND COUNTED ACCORDING TO THE TRYPON BLUE EXCLUSION METHOD.</p>	
V. INTERNATIONAL DEPOSITARY AUTHORITY	
<p>Name: Dr P J Packer ECACC CAMR</p> <p>Address: Porton Down Salisbury Wiltshire SP4 0JG</p>	<p>Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):</p> <p>Date: 30/5/00 P.J. Packer</p>

<sup>4</sup> Fill in if the information has been requested and if the results of the test were negative.



BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

TO

BAXTER AG  
INDUSTRIESTRASSE 67  
1220 VIENNA  
AUSTRIA

INTERNATIONAL FORM

NAME AND ADDRESS  
OF DEPOSITOR

<b>I. IDENTIFICATION OF THE MICROORGANISM</b>	
Identification reference given by the DEPOSITOR:  HYBRIDOMA CLONE 198/U2	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY:  99121620
<b>II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION</b>	
The microorganism identified under I above was accompanied by: <div style="margin-top: 10px;"> <input checked="checked" type="checkbox"/> A scientific description           <div style="margin-left: 20px;"><input type="checkbox"/> A proposed taxonomic designation</div> </div> (Mark with a cross where applicable)	
<b>III. RECEIPT AND ACCEPTANCE</b>	
This International Depository Authority accepts the microorganism identified under I above, which was received by it on 16 <sup>th</sup> December 1999 (date of the original deposit) <sup>1</sup>	
<b>IV. RECEIPT OF REQUEST FOR CONVERSION</b>	
The microorganism identified under I above was received by this International Depository Authority on (date of the original deposit) and A request to convert the original deposit to a deposit under the Budapest Treaty was received by it on (date of receipt of request for conversion)	
<b>IV. INTERNATIONAL DEPOSITORY AUTHORITY</b>	
Name: Dr P J Packer  Address: ECACC CAMR Porton Down Salisbury SP4 0JG	Signature(s) of person(s) having the power to represent the International Depository Authority or of authorized official(s):  Date: <i>PSH</i> 30/5/00

1 Where Rule 6.4(d) applies, such date is the date on which the status of international depository authority was acquired

## APPENDIX 3

Page 24

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

TO

BAXTER AG  
INDUSTRIESTRASSE 67  
1220 VIENNA  
AUSTRIA

## VIABILITY STATEMENT

Issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified on the following pageNAME AND ADDRESS OF THE PARTY  
TO WHOM THE VIABILITY OF STATEMENT  
IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
Name: BAXTER AG  Address: INDUSTRIESTRASSE 67 1220 VIENNA AUSTRIA	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:  99121620  Date of the deposit or of the transfer: 16 <sup>th</sup> December 1999
II. VIABILITY STATEMENT	
The viability of the microorganism identified under II above was tested on <sup>2</sup> . On that date, the said microorganism was <div data-bbox="82 1213 164 1268"><input checked="" type="checkbox"/></div> <sup>3</sup> viable <div data-bbox="82 1289 164 1344"><input type="checkbox"/></div> <sup>3</sup> no longer viable	

- 1 Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).
- 2 In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.
- 3 Mark with a cross the applicable box.